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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,975	03/23/2005	Keith L. Milliman	2861(2003-3492)	9050
7590	03/30/2007	Lisa J Moyles Senior Patent & Trademark Counsel Tyco Healthcare Group United States Surgical 150 Glover Avenue Norwalk, CT 06856	EXAMINER NASH, BRIAN D	ART UNIT 3721 PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	03/30/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/528,975	MILLIMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian Nash	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 February 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12,21-24 and 26-28 is/are rejected.
- 7) Claim(s) 25 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 March 2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/05</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION*****Examiner's Comments***

1. This action is in response to applicant's election received 2/12/2007.

Applicant elected Group I, claims 1-12 drawn to drawn to an anvil sub-assembly having a plurality of staple forming pockets, a cutting ring, and a retainer clip without traverse.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Additionally, applicant cancelled the non-elected claims 13-20. The pending claims are now 1-12 and 21-28.

***Specification***

2. The title of the invention is not descriptive and is therefore objected to. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested:  
**SURGICAL STAPLING DEVICE HAVING VISUAL INDICATOR IN HANDLE ASSEMBLY.**

***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15 and 18 of US 6,945,444.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because a person having ordinary skill in the art would have found the claims to have been obvious variations of the claims of the patents. The claims of the patent and the claims of the present application are both directed to a surgical stapling device having an indicator assembly. While the claims of the present application and the claims of the patents may have variations and differences in their scope and terminology, the variations and differences would have been obvious to one having ordinary skill in the art.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, there is insufficient antecedent basis for the terminology "the cartridge assembly".

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 9, 12, 21-22, 24 and 26-28 rejected under 35 U.S.C. 102(b) as being anticipated by US 4,379,457 to Gravener et al. Gravener et al shows the same surgical stapling device as claimed:

With respect to claims 1, 21 and 28, a handle assembly (left portion of Fig. 1) with firing trigger, a body portion (12), a head portion (right side of Fig. 1) having an anvil assembly (20) and a shell assembly (attached to anvil assembly – not numbered), an indicator (34) positioned on the handle

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assembly and having a bulbous shape (the curved outer surface of 34 resembles a bulbous or dome shape), the indicator is capable of moving between two positions, and a cartridge assembly (22); the indicator (34) is pivotally supported within bore (17) of the handle assembly as it turns with screw (35) in response to movement of the anvil via turning of the approximation mechanism.

With respect to claims 2 and 22, a lens (40) at least partially covering the indicator.

With respect to claim 3, an approximation mechanism (16) positioned within the handle assembly and extending at least partially through the body portion (12) and having a distal end adapted to engage the anvil assembly, the approximation mechanism moveable within the stapling device so as to move the anvil assembly between two positions in relation to the shell assembly (see column 5, lines 60+).

With respect to claim 4, the approximation mechanism (16) is operably associated with the indicator (34) such that movement of one affects the other.

With respect to claims 5 and 24, a slide member (37) operably associated with the indicator (34) and moveable within the handle assembly between two positions.

With respect to claims 9 and 26, the indicator (34) is pivotally supported within bore (17) of the handle assembly as it turns with screw (35).

With respect to claim 12, the shell assembly (attached to anvil assembly – not numbered) supports the cartridge assembly (22) which contains an annular array of staples.

With respect to claim 27, the indicator (34) pivots in both clockwise and counter-clockwise directions in response to turning the approximation mechanism (16) in order to position the anvil to a desired position.

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

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subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-2 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,275,322 to Brinkerhoff et al.

With respect to claim 1-2 and 21-22, Brinkerhoff et al shows the same surgical stapling device substantially as claimed including a handle assembly (80), firing trigger (86), body portion (70), head portion having an anvil, cartridge and shell assembly that are moveable in response to an approximation mechanism (82) in the handle assembly (see Fig. 1), and an indicator (85 – see Figs. 1,15) moveable between two positions in response. Brinkerhoff et al does not show the indicator to have a bulbous or dome shape; however, It would have been an obvious matter of design choice to modify the indicator window (84) of Brinkerhoff et al since applicant has not disclosed that having a bulbous or dome shaped indicator solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with either design choice.

With respect to claim 23, the indicator (85) extends beyond a top surface of the handle assembly (see Fig. 1)

***Allowable Subject Matter***

11. Claim 25 is objected to as being dependent upon a rejected base claim, but appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
12. Claims 6-8 and 10-11 appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Refer to attachment (PTO-892) for notice of references cited and recommended for consideration based on their disclosure of limitations of the claimed invention.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is 571-272-4465. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 6 p.m.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at 571-272-4467. The official fax number for this Group is: 571-273-8300

16. Information regarding the status of an application may be obtained form the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/28/2006



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